

Appendix A

Environmental Lead and Exposure Trends

Appendix A

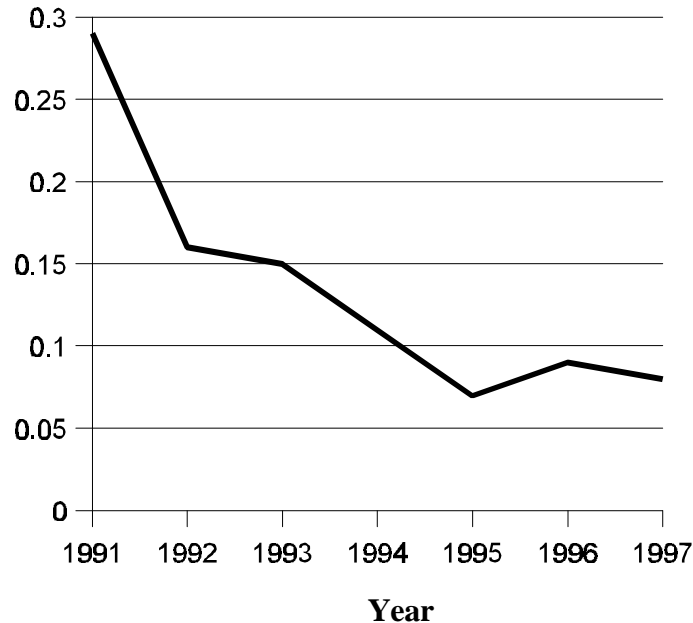
Environmental Lead and Exposure Trends

Environmental Lead Trends

Over the past several years, exposure to lead from environmental media (food, water, and air) has declined, and average blood lead levels in the population have declined as well. Today, at most air monitoring sites in California, concentrations of lead in the ambient air are far less than the State Ambient Air Quality Standard of $1.5 \mu\text{g}/\text{m}^3$ over a 30-day averaging time. At criteria pollutant monitoring network sites (State/Local Air Monitoring Stations (SLAMS) or National Air Monitoring Stations (NAMS) which are intended to represent population exposure), the highest monthly means have dropped from $0.29 \mu\text{g}/\text{m}^3$ in 1991 to $0.08 \mu\text{g}/\text{m}^3$ in 1997. Figure A-1 shows the monthly mean lead concentration at the highest criteria pollutant monitoring site in the State from 1991 to 1997. The site with the highest monthly mean would not necessarily be the same site from year to year.

Figure A-1: Statewide Maximum Monthly Mean Lead Concentrations

Air Concentration ($\mu\text{g}/\text{m}^3$)
Monthly Mean



Another way to characterize the ambient concentration decreases is to look at the number of times per year that the monthly mean exceeded $0.10 \mu\text{g}/\text{m}^3$ at SLAMS/NAMS stations. This is summarized in Table A-1.

Table A-1
Number of Site-Months with Lead Concentrations¹ $\geq 0.10 \mu\text{g}/\text{m}^3$

Year	Number at or over $0.10 \mu\text{g}/\text{m}^3$
1991	19
1992	7
1993	3
1994	3
1995	0
1996	0
1997	0

¹ at SLAMS/NAMS sites

Some special purpose monitors located near large sources or locations potentially affected by historic emissions have detected higher concentrations. Monthly mean concentrations up to $1.83 \mu\text{g}/\text{m}^3$ at one site in 1993 and $3.98 \mu\text{g}/\text{m}^3$ at another in 1994 have been measured. These values are believed to be the result of unusual events or conditions.

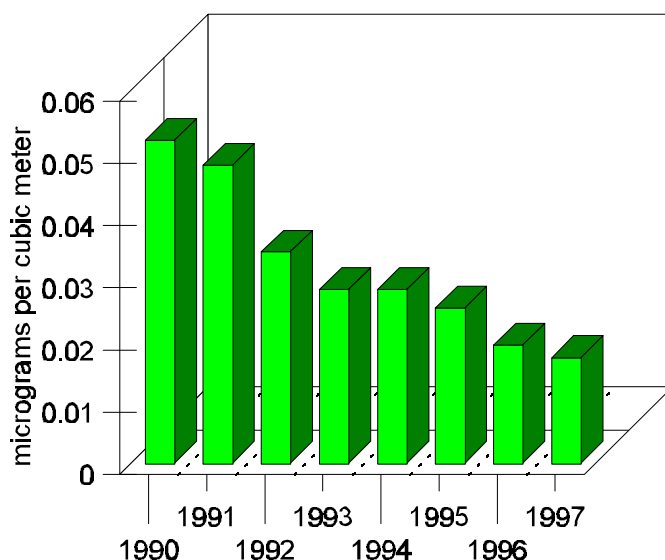
The statewide population-weighted annual mean concentrations of lead in the ambient air have dropped precipitously over the last 20 years. Figure A-2 shows the reduction in the statewide population-weighted annual mean air lead concentrations for the years 1990 to 1997.

Annual mean lead levels higher than the surrounding urban background concentrations of 0.01 to $0.03 \mu\text{g}/\text{m}^3$ have been measured in industrial areas which are near large lead processing facilities and major freeways. These higher than average levels have occurred despite the current use of highly effective lead emission controls on the facilities. The sources and district continue to monitor and address the cause(s) of the air lead levels above background.

Blood Lead Level Trends

The U. S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) has investigated the distribution of blood lead levels (BLLs) in the United States population using large cross-sectional national surveys. These studies have shown decreasing BLLs over the last two decades.

**Figure A-2: Statewide Population-Weighted
Annual Mean Lead Levels**



The second National Health and Nutritional Examination Survey (NHANES) II was conducted from 1976 to 1980. The population was surveyed again from 1988 to 1991 for NHANES III, phase 1 and from 1991 to 1994 for phase 2. These large-scale studies have documented an overall decrease in blood lead levels of 78 percent for persons aged 1 to 74 years between NHANES II and NHANES III, phase 1. In the NHANES II study, an estimated 88.2 percent of one to five year old children in the United States had blood lead levels greater than or equal to (\geq) 10 $\mu\text{g}/\text{dL}$. In phase 1 of the NHANES III survey, 8.9 percent of 1 to 5 year old children were determined to have blood lead levels \geq 10 $\mu\text{g}/\text{dL}$. Table A-2 illustrates the changes in the blood lead distributions between phases 1 and 2 of the NHANES III survey for children 1 to 2 years old and for children up to age 7.

Table A-2
Comparison of Results from NHANES III Phases 1 and 2

	Phase 1	Phase 2	Phase 1	Phase 2
Children aged 1- 2 yrs	Nationwide		Western Region	
Total sampled	924	987	308	218
Geometric mean BLL, µg/dL	4.05	3.14	3.39	2.40
Geometric standard deviation, µg/dL	2.06	2.09	1.96	2.03
# with blood leads over 10 µg/dL (%)	123 (13)	67 (7)	24 (8)	6 (3)
# with blood leads over 15 µg/dL (%)	46 (5)	22 (2)	6 (2)	1 (0)
Children aged 0 - 7 yrs				
Total sampled	2,506	2,619	891	585
Geometric mean BLL, µg/dL	3.31	2.7	2.49	2.18
Geometric standard deviation, µg/dL	2.15	2.09	2.08	1.94
# with blood leads over 10 µg/dL (%)	271 (11)	160 (6)	49 (5)	13 (2)
# with blood leads over 15 µg/dL (%)	87 (3)	51 (2)	9 (1)	2 (0)

Appendix B

Census State Data Centers and Instructions For Retrieving Data

Appendix B

Census State Data Centers

In this Appendix, we list the designated Census State Data Centers for the U.S. Census. These are organizations that can help districts and permit applicants obtain data from the census files.

Census State Data Centers: California

Census State Data Center-Department of Finance
915 L Street
Sacramento, CA 95814
Ms. Linda Gage, Director
(916) 322-4651
Mr. Richard Lovelady
(916) 323-4086
FAX (916) 327-0222
filgage@dof.ca.gov
<http://www.dof.ca.gov/html/Demograp/internet/druhpar.htm>

Sacramento Area COG
3000 S Street, Suite 300
Sacramento, CA 95816
Kelly Grieve
(916) 457-2264
FAX (916) 457-3299
kgrieve@sacog.org
<http://www.sacog.org>

Association of Bay Area Governments
Metro Center
8th and Oak Streets
P.O. Box 2050
Oakland, CA 94604-2050
(510) 464-7937
FAX (510) 464-7970
<http://www.abag.ca.gov>

Southern California Association of Governments
818 West 7th Street, 12th Floor
Los Angeles, CA 90017
Mr. Javier Minjares
(213) 236-1800
minjares@scag.ca.gov

San Diego Association of Governments
Wells Fargo
401 B Street, Suite 800
San Diego, CA 92101
Ms. Karen Lamphere
(619) 595-5300
kla@polaris.sandag.cog.ca.us

State Data Center Program
University of California-Berkeley
2538 Channing Way #5100
Berkeley, CA 94720-5100
Ms. Ilona Einowski/Fred Gey
(510) 642-6571
archive@ucdata.berkeley.edu

Association of Monterey Bay Area Governments
445 Reservation Road, Suite G
P.O. Box 809
Marina, CA 939-0809
Christy Oosterhous
Mr. Jim Werle
(408) 883-3750
ambag@mbay.net

Instructions for Retrieving Census Data on the Internet

The census access is set up to retrieve summary statistics on several levels, such as State, County, census tract, zip code. The following instructions give step-by-step guidance for obtaining the data needed to determine the appropriate exposure scenario for a Tier I assessment of neurodevelopmental risk.

In your web browser, go to <http://homer.ssd.census.gov/cdrom/lookup>.

Before you can obtain information for the affected census tract(s), you must have done the air dispersion modeling to identify the location of the maximum off-site air concentration and determined which census tract(s) are within ½ kilometer of that location. One can purchase the data to be used with GIS Software to graph the location of the census tract boundaries or consult the state data centers

To obtain the data for the census tract(s), go to the census website at <http://homer.ssd.census.gov/cdrom/lookup>, choose STF3A to open the next page. There, select California and mark “go to Level State--County (*Tracts and Block Groups)” and click on submit. At this page, select the county in which the facility is located or the county in which the affected neighborhood is located if different than the facility location and mark “go to level State--County--Census Tract (*Block Groups).” When you click on submit, this will bring up a listing of census tracts from which you can select the tract or tracts in which the maximum exposure area is located. Select the census tract(s), mark “retrieve the areas you’ve selected below,” click submit, choose “Tables to retrieve” and click submit again. On the list of Tables that comes up, select P121 ratio of income in 1989 to poverty level, universe:persons for whom poverty status is determined and H25A Median year structure built, universe: housing units. When you click submit, you will be asked to specify the format for the data. HTML is easy to read and will give you something like the following:

Database: C90STF3A
Summary Level: State--County--Census Tract

Tract 1043: FIPS.STATE = 06, FIPS.COUNTY90 = 037, FIPS.TRACT90 = 1043

RATIO OF INCOME IN 1989 TO POVERTY LEVEL

Universe: Persons for whom poverty status is determined

under .50.....	867
.50 to .74.....	816
.75 to 0.99.....	246
1.00 to 1.24.....	801
1.25 to 1.49.....	635
1.50 to 1.74.....	267
1.75 to 1.84.....	598
1.85 to 1.99.....	486
2.00 and over.....	3775

MEDIAN YEAR STRUCTURE BUILT

Universe: Housing units

Median year structure built.....	1958
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To calculate the percentage of the persons with an income less than 1.25 times the poverty level, you would sum the numbers of persons in the first 4 categories, divide by the sum of the

people in all the categories, and multiply by 100. In this example, the sum of the first 4 categories is 2730 and the sum of all the categories is 8491. $2730/8491 = 0.322$ or 32 percent. This census tract has both a median age of housing older than 1960 and more than 30 percent of the population with an income less than 1.25 times the poverty level so this is a high exposure area.

Appendix C

Baseline Blood Lead Levels and Exposure Scenarios

Appendix C

Baseline Blood Lead Levels and Exposure Scenarios For the Tier I Analysis

Selecting a Geometric Mean and Geometric Standard Deviation to Represent the High and Average Exposure Scenarios

Increased exposure to lead will increase the blood lead of exposed persons. The Office of Environmental Health Hazard Assessment (OEHHA) has found that there is no evidence of a threshold for neurodevelopmental effects and has provided a slope factor relating the air lead to the blood lead levels (BLLs). In terms of the significance of blood lead concentration for an individual, the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (CDC) has identified a BLL in children of 10 µg/dL as a level of concern and has recommended that regulatory efforts should be directed to minimizing the number of children with BLLs at or over this level. (CDC, 1991)

Because lead from multiple sources can impact the BLLs of children, an evaluation of the effect of a given level of air lead emissions on BLLs in a population of children requires knowledge about the distribution of baseline BLLs. These reflect the contribution of other sources and body burdens due to previous exposure to all sources. There will be a range of BLLs in any population that will reflect the various sources of exposure plus behavioral (e.g. mouthing behavior) and physiological factors such as nutritional status.

What are the geometric mean and the geometric standard deviation and why are they important?

BLLs have been found to be log-normally distributed; that is, the BLLs do not fit the normal distribution but the natural logarithms of the BLLs do. Therefore, when the values are transformed to their log equivalents, the statistical tools developed for the normal distribution can be used with them. Thus, the geometric mean (GM) and geometric standard deviation (GSD) can be used to find the percentage of the distribution above a specific value in the same way that the mean and standard deviation are used with a normal distribution. The GM and GSD describe the shape of the curve and can be used to calculate the percent of the population (or probability of an individual in the population) having a BLL of 10 µg/dL or more.

We are using BLLs of 10 µg/dL in these Guidelines as the primary benchmark for decision-making consistent with CDC's recommendation that regulatory efforts be directed at minimizing the number of children with BLLs at or over this level.

The GM describes the midpoint of the distribution while the GSD describes the spread of the distribution. In two distributions with the same GM, the one with the larger GSD will have a greater percentage of values ≥ 10 µg/dL. The spread of the distribution of BLLs reflects the variability for a given population.

There are two sources of variability: the environmental variability and the inter-individual variability. The environmental variability stems from the variability in the soil, dust, air, water, food, and other sources of exposure. The inter-individual variability can be calculated by grouping all the children of the same age exposed to the same environmental concentrations and calculating a GSD for each group. This technique can be used to generate a site-specific inter-individual GSD. A site specific inter-individual GSD takes into account factors such as the bioavailability of the lead in the soil and dust. It describes the effect of the behavioral and physiological factors mentioned above for a specific location. The United States Environmental Protection Agency (U.S. EPA) has recommended the use of an inter-individual GSD of 1.6 for estimating risk using the Integrated Uptake Exposure Biokinetic (IEUBK) Model for Lead in Children. The IEUBK is a model used to predict BLLs when the environmental concentrations are known.

How does geometric mean and geometric standard deviation relate to estimating risk?

We have proposed that neurodevelopmental risk from lead be defined as the probability of children in the Maximum Exposure Area (MEA) having BLLs $\geq 10 \mu\text{g/dL}$. We arrived at this recommendation after evaluating several other ways of evaluating risk.

We have proposed three tiers of analysis for estimating risk. Tier I is a generic approach that requires minimal site-specific information on concentrations of lead in environmental media other than air. Tier II relies on site-specific measurements of lead in dust and soil and the IEUBK Model to generate predicted BLLs. Tier III involves actual blood lead sampling to define the baseline BLLs.

As testing to determine every person's blood lead level may be impractical, the Tier I analysis offers a reasonable alternative. However, providing this approach requires that we identify baseline BLLs. We evaluated three approaches to defining baseline BLLs for the Tier I option. The first approach is to use a GM and GSD based on evaluating data gathered over a large geographic region, referred to as a regional approach. The second approach is based on using the inter-individual GSD to calculate risk to the individual living at the location with the highest air concentration caused by the emissions from the facility, known as the maximum individual risk. The third approach is to calculate risk to the population living within a certain geographical distance of the location with the highest air concentration caused by the facility. This is characterized as the neighborhood approach.

The regional approach

The best data available on BLLs in the United States was developed by the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, in the third National Health and Nutrition Examination Survey (NHANES III). The NHANES III data give a GM and GSD that is representative of the population of the U.S. and certain

subgroups (i.e. the people of the western region). These data are based on representative sampling of thousands of people across the country. Data from this survey are referred to as regional data because it is gathered over a large geographical area. As such, it is problematical for evaluating facility impact because it may incorporate greater variability in environmental concentrations than would be likely in a smaller area impacted by emissions from a single facility. It is likely that there is a greater variation in environmental concentrations regionally than would be seen in a community or neighborhood.

The maximum individual approach

In calculating risk from a single facility, we can look at the increased risk to the individual exposed to the highest concentration (maximum individual risk) or to the population in general. Cancer risk is characterized in both of these ways. The calculation of maximum individual risk requires a different approach to defining baseline BLL than a population-based approach. For the maximum individual risk approach, the appropriate GSD would be the inter-individual GSD when the concentrations in air, water, soil, and dust are known. Population risk can be expressed two ways. One, as the number of children in the population expected to have BLLs ≥ 10 $\mu\text{g/dL}$ or two, as the individual average probability of any child in the population having a BLL ≥ 10 $\mu\text{g/dL}$.

When the environmental concentrations are not known, as in a Tier I analysis, one must either choose a larger GSD or choose a baseline blood lead concentration to account for high environmental concentrations and sensitive populations. The use of the mean of a distribution such as NHANES for a baseline blood lead concentration would not be health protective because at the mean, half of the children would have higher baseline BLLs. We could choose to use the BLL that represents some other percentage of the distribution, such as the 90th, 95th, or 99th percentile blood lead. However, those choices could be too restrictive given that they would incorporate the assumption that all sources of elevated blood leads are at the high end of the range at the locations being evaluated. These concerns led us to consider a third approach.

The neighborhood approach

The neighborhood approach looks at the average individual risk for a child in the maximum exposure area resulting from the facility emissions. To evaluate the feasibility of this approach, staff sought studies of BLLs in communities to evaluate whether there was any difference in GSD between regional, community, or neighborhood populations and to identify appropriate BLL statistics for each exposure scenario. The results of this analysis are given below.

What BLL studies were evaluated?

Published reports of 20 environmental health studies in which lead exposure was a concern were carefully evaluated. They are listed in Table C-1 and full citations are given at the

Table C-1 Twenty Environmental Health Studies

1. Palmerton Lead Exposure Study
2. Multisite Lead and Cadmium Exposure Study with Biological Markers Incorporated
3. Biological Indicators of Exposure to Lead RSR Smelter Site in Dallas, Texas
4. The Third National Health and Nutrition Examination Survey (NHANES III)
5. Bingham Creek Environmental Health Lead and Arsenic Exposure Study
6. Leadville / Lake County Environmental Health Lead Study
7. Midvale Community Lead Study
8. Lead and Cadmium Exposure Study, Galena, Kansas
9. Evaluation of the Risk from Lead and Arsenic, Sandy, Utah
10. The Butte- Silver Bow County Environmental Health Lead Study
11. The Impact of a Los Angeles County Stationary Lead Source on the Blood Lead Levels of Children Living Nearby
12. Missouri Respiratory Study: Forest City and Glover, Missouri
13. Cherokee County Kansas Lead Surveillance Program
14. The Relationship of Human Levels of Lead and Cadmium to the Consumption of Fish Caught In and Around Lake Coeur D'Alene, Idaho
15. A Cohort Study of Current and Previous Residents of the Silver Valley; Assessment of Lead Exposure and Health Outcomes
16. McClellan Air Force Base Cross-Sectional Health Study, Sacramento
17. Ottawa County Blood Lead Testing Project
18. Health Study of Communities Surrounding OTIS Air National Guard Base/Camp Edwards Falmouth, Massachusetts
19. Study of Disease and Symptom Prevalence in Residents of Yukon and Cokesburg, Pennsylvania
20. Lead and Mercury Exposure Screening of Children in Pompton Lakes

end of this Appendix. Most of these studies examined BLLs or other indices of exposure in small towns or cities with known stationary sources of lead exposure. Many of these sources no longer operate and some have been closed for 60 years or more.

In the first 11 of these studies, the researchers made systematic measurements of blood lead levels in children less than 7 years of age. In the other 9, the researchers either did not take representative samples, did not include children, or used another index of exposure. In 10 of the first 11 studies, the researchers measured BLLs in neighborhoods or communities. The NHANES III data, by contrast, were gathered for selected Census Blocks throughout the country

and not specifically for source impacted populations. In 3 of the 10 studies, the community was segmented into smaller areas. In 4 studies, neighborhoods were selected to represent certain exposure conditions. In the other 3, either multiple communities or a whole community were sampled. The 3 studies in which the neighborhoods are segments of the community were useful for researching the question of whether the GSD for a community is necessarily larger than the GSD for a neighborhood as has been suggested. For the purposes of this analysis, we defined a neighborhood as an area less than 3 squared kilometers (km^2) and a community as an area of more than 3 km^2 and less than 200 km^2 . However, as we will show later in this Appendix, we found that community BLLs did not differ from neighborhood BLLs when the number of children sampled was greater than 50.

The spread in a set of measurements, such as BLLs, is described in the GSD. The spread of the data represents the variability in the BLLs and reflects a number of factors. Among them are the environmental concentrations and behavioral factors that result in ingestion of soil and dust, physiological and chemical factors that affect absorption of inhaled or ingested lead, previous exposure, and measurement variability. To use the GM and GSD from one population to predict the percent of BLLs $\geq 10 \mu\text{g/dL}$ in another population, one must have reasonable confidence that there is enough similarity in the two populations with regard to the factors affecting the variability and exposure.

Commenters on previous drafts of this document have said that the greatest variability would be seen in regional BLL studies and that the use of the regional data would overstate the risk for an individual or neighborhood impacted by a specific facility. In regional BLL studies, GSDs ranged from 1.92 to 1.99 in 4 subsets from the Multisite Lead and Cadmium Study which collected data from communities in four states. In the NHANES survey, the GSD for white children in the Western Region was 1.74, the GSD for black children was 2.08, and the GSD for all children in the Western Region was 1.94.

Community studies showed GSDs ranging from 1.51 to 2.12, with the median at 1.68. These community GSDs were not universally lower than the GSDs from the regional studies. The distribution of GSDs for the regional studies was congruent with the upper quartile of the community studies and of the neighborhood studies. To evaluate which studies should be considered in defining the baseline BLLs, we also examined the GSDs for communities as compared to neighborhoods. Tables C-2 and C-3 show the GSDs for the communities and neighborhoods, respectively.

Overall, neighborhood GSDs ranged from 1.13 to 2.07 with the median at 1.62 as compared to the community studies with a range from 1.51 to 2.12 with a median at 1.68. Within individual studies we can see that the neighborhood GSDs ranged fairly widely around the community GSD. Table C-4 gives statistics for the 3 studies in which the community was divided into smaller areas (Leadville, Bingham Creek, and Palmerton) and for Butte where selected neighborhoods were sampled. The median of the neighborhood GSDs were lower than

Table C-2 Community Geometric Standard Deviations

Study Location (Data Set Used)	GSD
Dallas, Texas (area 3)	1.51
Los Angeles (gradient graphical treatment for values above 5)	1.55
Los Angeles (analytic method for values above 5)	1.55
Bingham Creek, Utah (all)	1.56
Dallas, Texas (areas 1-4)	1.66
Dallas, Texas (area 2)	1.66
Palmerton, Pennsylvania (all)	1.67
Galena, Kansas (unexposed comparison)	1.68
Dallas, Texas (areas 1-5)	1.68
Dallas Texas (area 5, unexposed comparison)	1.76
Leadville, Colorado (all)	1.77
Butte, Montana (all)	1.81
Galena, Kansas (exposed)	2.12
Los Angeles (complete data set)	unavailable

the community or cumulative GSDs. However, neighborhood GSDs are not necessarily lower than community GSDs.

As can be seen in Table C-3, the data show a clear association between small sample size and lower GSDs. If we only look at neighborhoods in which the sample size exceeds 50, we see the range of GSDs is much smaller (from 1.45 to 2.07) with the median at 1.63. This range is very similar to the range for community GSDs. If we look at the neighborhoods with a sample size less than 50, we see the range is from 1.13 to 2.16 with a median at 1.57. This does not appear to be a function of area size because the GSDs for the neighborhoods with areas less than 0.5 km² have GSDs ranging from 1.5 to 1.83. The data indicate that neighborhood GSDs are not generally lower than community GSDs when sample sizes are over 50. Therefore, we are excluding those neighborhoods or communities with sample sizes less than 50 to avoid shortcomings associated with small samples.

Table C-3 Neighborhood Geometric Standard Deviations

Number sampled > 50			Number sampled < 50		
Study Location (Data Set Used)	GSD	N	Study Location (Data Set Used)	GSD	N
Bingham Creek (area G)	1.45	99	Bingham Creek (area K)	1.41	43
Bingham Creek (area A)	1.48	96	Palmerton (area F)	1.45	13
Bingham Creek (area C)	1.49	118	Palmerton (area K)	1.45	16
Dallas (area 4)	1.51	70	Leadville (area B)	1.47	21
Bingham Creek (area D)	1.52	187	Butte (area E)	1.5	27
Bingham Creek (area F)	1.6	156	Butte (area F)	1.52	17
Bingham Creek (area B)	1.62	117	Palmerton (area E)	1.54	19
Bingham Creek (area E)	1.63	60	Leadville (area F)	1.55	20
Sandy	1.63	105	Leadville (area G)	1.55	39
Midvale (all)	1.66	181	Palmerton (area C)	1.57	19
Leadville (area C)	1.72	91	Butte (area G)	1.62	13
Leadville (area D)	1.76	72	Palmerton (area G)	1.63	19
Midvale (random)	1.77	112	Palmerton (area J)	1.66	9
Butte (area A)	1.84	183	Butte (area B)	1.67	15
Bingham Creek (area H)	2.00	56	Bingham Creek (area I)	1.7	33
Dallas (area 1)	2.07	53	Leadville (area M)	1.72	11
			Palmerton (area A)	1.72	8
Number sampled < 50			Butte (area D)	1.79	11
Study Location (Data Set Used)	GSD	N	Palmerton (area D)	1.8	20
Bingham Creek (area J)	1.13	4	Leadville (area E)	1.83	11
Palmerton (area I)	1.15	3	Butte (area C)	1.89	12
Leadville (area H)	1.29	19	Palmerton (area H)	1.92	12
Palmerton (area B)	1.37	2	Leadville (Area A)	2.16	31

Table C-4 Comparison of Community Geometric Standard Deviation to Neighborhood Geometric Standard Deviation

Study	Community GSD	Range of Neighborhood GSDs	Median of Neighborhood GSDs
Palmerton	1.67	1.15 - 2.07	1.57
Bingham Creek	1.56	1.13 - 2.00	1.52
Leadville	1.77	1.47 - 2.16	1.72
Butte	1.81	1.50 - 1.89	1.73

How will the GMs and GSDs be used?

Because there are some neighborhoods where high numbers of older housing and low incomes can result in high baseline BLLs, we are proposing that the Tier I screening approach include two exposure scenarios. Thus, we need to select GMs and GSDs to represent the high baseline BLLs, and the average baseline BLLs. This approach protects populations with a high potential for exposure due to other sources without imposing excessive requirements on facilities that are not so located.

Ideally, the GMs and GSDs should be chosen from studies that have environmental characteristics similar to the areas they are being used to represent. However, we do not have adequate data to make a choice on that basis. The factors that have been most consistently associated with elevated BLLs are low income and lead in paint, soil, and dust. Additional factors that moderate the association with lead in soil and dust are accessibility of the soil and the contribution to the dust of soil and paint. Only 2 of the studies were conducted in areas with climatic conditions similar to most of California and in areas potentially affected by sources similar to those with the highest known emissions in California.

In the study of Hacienda Heights BLLs (Los Angeles County), dust lead concentrations were generally low with less than 1 percent of the samples greater than 400 ppm. There were also fewer than 1 percent of the children with BLLs $\geq 10\mu\text{g/dL}$. This is less than half of the two percent found in NHANES III Phase 2 to be representative of the population of the children in the Western region. Therefore, it is reasonable to conclude that Hacienda Heights is not representative of a high exposure scenario despite the presence of a large lead smelter in the area. In Dallas Area A (the high air exposure area), many of the homes had the contaminated soil removed and replaced. This remediation may make the Dallas Area A lead data set unrepresentative of a typical high exposure scenario.

Since none of the studies are representative of the high exposure scenario on the basis of physical and demographic characteristics, we considered choosing a set of statistics based on the level of risk indicated by the BLLs. We calculated the percentage of children with BLLs $\geq 10\mu\text{g/dL}$ for

each data set. Then we determined what risk level would be representative of each exposure scenario. The U.S. EPA considers 5 percent the upper bound of the probability that would be considered to “pose a threat”. Two neighborhoods have statistics that would fit this criteria for a high exposure area; Area C in Leadville (GM = 4.12 µg/dL and GSD = 1.72), and Area A in Butte (GM = 3.69 µg/dL and GSD = 1.84). Soil and dust lead levels in these areas are higher than would be expected in California. However, because there is some question of lower bioavailability and lower probability of exposure in these areas, we propose to use one of these statistical sets for the high exposure scenario even though the environmental concentrations may not be representative of California.

One would expect a higher GSD in an area impacted by a variety of sources. Two examples that illustrate this are areas F and H in Leadville. The GMs in these 2 areas, 6.64 µg/dL and 6.92 µg/dL respectively, are among the highest in Leadville clearly indicating high exposure while the GSDs, 1.55 and 1.29 respectively, are among the lowest. Both are areas in which no exposure due to lead in paint would be expected because both are mobile home parks.

In consideration of all the above and the expectation that high exposure areas in California will be impacted by a variety of source types, we propose that a GM of 3.69 µg/dL and a GSD of 1.84 be used to characterize the high exposure scenario. This yields a probability of having a BLL $\geq 10\mu\text{g/dL}$ of 5 percent.

For the average exposure scenario, we propose the use of statistics from the studies that would result in a probability of 2 percent. The two areas closest to that target level were the low air dispersion area of Dallas, Texas with a GM of 4.56 µg/dL, a GSD of 1.51, and a probability of 2.87 percent; and the comparison area for Galena, Kansas with a GM of 3.13 µg/dL, a GSD of 1.68, and a probability of 1.25 percent. Both of these areas have relatively low dust and soil lead levels. However, the mean BLL for Dallas, Texas is much higher than would be expected in an average population as seen in the NHANES III study. Therefore, we have chosen the statistics from the Galena, Kansas comparison area to represent the baseline blood lead distribution for the average exposure scenario.

Table C-5 shows the statistics we have chosen to use in the Tier I approach to estimating neurodevelopment risk.

Criteria for Selecting the Appropriate Exposure Scenario for a Tier I Screening Analysis

The probability of a child having a BLL $\geq 10\mu\text{g/dL}$ is dependent upon a number of factors, such as exposure to lead in dust, soil, food, water, and air. In a Tier I situation, we will not know the environmental lead concentrations. The air dispersion modeling only gives the additional air exposure and the aggregate model incorporates the secondary exposure in soil and dust due to the modeled air emissions. It neither completely characterizes the concentrations in

Table C-5 Default Statistics for Tier I Neurodevelopmental Risk Estimation

	GM ($\mu\text{g/dL}$)	GSD
High Exposure	3.69	1.84
Average Exposure	3.13	1.68

the air nor in the soil and dust due to other influences (other sources, paint, historical deposition) on these environmental concentrations. In addition, BLLs are influenced by body burden of lead due to previous exposure, behavioral and physiological factors, the bioavailability of the lead and anomalous sources which can not be known in the context of a screening analysis.

Some known factors have been shown in numerous studies to be associated with higher blood lead levels. One is lead in paint, another is socio-economic status. What is needed for a generic approach is a simple set of criteria using data that are easily obtained and verified.

Therefore for the Tier I analysis, we recommend using age of housing and income as the criteria for choosing an appropriate exposure scenario. Lead in paint has been found to be related to age of housing in a nationwide survey by the Department of Housing and Urban Development (HUD). Table C-6 below illustrates that relationship and is excerpted from a table based on that survey that was presented in "Screening Children for Lead and Managing Childhood Lead Poisoning in California - Recommendations to the California Department of Health Services and Technical Report from the Science and Policy Advisory Panel to the CDHS Childhood Lead Poisoning Prevention Branch (CLPPB), January 1997." As you can see from the data in Table C-6, homes built before 1960 have a much greater probability of having high lead levels in paint than homes built between 1960 and 1979.

Table C-6 Percentage of Occupied U.S. Homes with Lead-Based Paint by Lead Concentration and Year Constructed

Construction Year	Percentage of homes (%) with specified paint lead concentrations			
	≥ 0.7 (mg/cm^2)	≥ 1.0 (mg/cm^2)	≥ 1.2 (mg/cm^2)	≥ 2.0 (mg/cm^2)
1960-1979	80	62	47	18
1940-1959	87	80	74	52
before 1940	94	90	79	75
all homes before 1979	86	74	63	43

The CDHS surveyed homes in 3 urban areas in California. This survey found that overall 71 percent of homes built before 1950 had exterior paint lead levels $\geq 5,000$ ppm compared to 16 percent of post-1950 homes. Thirty-one percent of homes built before 1950 had interior paint lead levels $\geq 5,000$ ppm compared to 7 percent of post-1950 homes. Therefore, the likelihood of elevated lead levels will be greater in neighborhoods with a preponderance of homes built before 1950. Since virtually no lead paint is likely to be found in homes built after 1980, the risk from lead in paint is likely to be lower in neighborhoods where most (or all) of the homes were built after 1980.

Based on the findings of these two surveys, it appears that houses built before 1950 pose greater potential to contribute to high baseline blood lead levels than those built between 1950 and 1980. According to the 1990 census data, the median age of housing statewide is 1967 and the associated fraction of housing built before 1950 is 20 percent. A sampling of individual census tracts indicated a median of 1960 is associated with up to 30 percent of housing built before 1950.

Low socioeconomic status is also associated with higher overall lead levels. Income is only one aspect of socio-economic status but has an impact on nutritional status (which affects lead adsorption in the body) and on the likelihood that lead paint will be either in poor condition or removed by someone other than a certified lead paint abatement contractor.

We considered 4 approaches for setting the income criteria. One was a percentage of families with incomes below a specific amount. Another was comparison of the median income for the census tract to a specific amount. A third was relating the median income to the median income for the County. A fourth was the percentage of the population with incomes below the poverty level. Using an index value of a set dollar amount would require periodic review and adjustment to account for inflation. In addition, use of a single value statewide would result in an inequity between counties where the cost of living differed significantly. A relative measurement based on income would not take into account family size which has a large impact on the amount of money available for food and home maintenance. Therefore, we propose that a census tract be designated as high risk if the percentage of the population with incomes less than 1.25 times the poverty level was 30 percent or more and the median age of housing is 1960 or earlier.

The selection of a ratio of income to poverty level of 1.25 was based on the limitations of the reasonably available census data which uses categories in which the nearest break is at 1.25 times the poverty level. The choice of a 30 percent proportion was based on this consideration and research using the NHANES data (Pirkle, 1998). In this analysis, the researchers looked at mean BLLs and how they were related to selected demographic characteristics. Among those demographic characteristics was income. Dr Pirkle found that among children 1-5 years old the incidence of blood leads ≥ 10 $\mu\text{g}/\text{dl}$ was 8.0 percent in children in the low income category compared to 1.9 percent for the middle income group and 1.0 for the high income group. Dr Pirkle used a poverty to income ratio of 1.3 times the poverty level to define 'low income'. Using this data we estimated that if about half of the children were at a poverty to income ratio of 1.3, the percentage of BLLs ≥ 10 $\mu\text{g}/\text{dl}$ would be about 5 percent. The BLLs could range from

5 to 8 percent in census tracts with a 50 percent or greater proportion of low income children. Given that the closest income to poverty ratio we could easily obtain from the census data was 1.25 percent and that a higher proportion of children than of adults are poor, we selected a 30 percent proportion as a criteria to identify high exposure areas. Based on the 1990 census data, this designation would apply to 273 of the 1637 census tracts in Los Angeles County.

The U.S. Census Bureau provides a good source of data on income and age of housing for each census tract on its website at <http://venus.census.gov/cdrom/lookup>. In the census data tables, age of housing is given in 2 ways; as number of housing units built within 1 of 8 ranges of year built, or as the median for the census tract. The ratio of income to poverty level is given as the number of persons in each of 8 categories. From this data you would have to calculate the percentage of persons with incomes less than the poverty ratio as shown in Appendix B.

REFERENCES

CDC, 1991, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Preventing Lead Poisoning in Young Children, October 1991.

Pirkle, 1998, James Pirkle, et al. Exposure of the U.S. Population to Lead, 1991-1994, Environmental Health Perspectives, Vol 106, November, 1998

STUDIES CITED

Dr. Robert L Bornschein, PhD, Advanced Geoservices Corp. Northeastern Pennsylvania Vector Control University of Cincinnati, Palmerton Lead Exposure Study Fall, 1994, Performed for the Palmerton Environmental Task Force, October 1996

U.S. Department of Health and Human Services Public Health Service, Agency for Toxic Substances and Disease Registry, Multistate Lead and Cadmium Exposure Study With Biological Markers Incorporated, April 1995. PB# 95-199188

U.S. Department of Health and Human Services Public Health Service, Agency for Toxic Substances and Disease Registry. Biologic Indicators of Exposure to Lead RSR Smelter Site Dallas, Texas, City of Dallas Department of Health and Human Services, September 1995, PB# 95-265500.

Data from the Third National Health and Nutrition Examination Survey (NHANES III) from Air Resources Board, Technical Support Document Proposed Identification of Inorganic Lead as a Toxic Air Contaminant Part B Health Assessment, Chapter 5, March 1997.

Department of Environmental Health University of Cincinnati, Bingham Creek Environmental Health Lead and Arsenic Exposure Study Final Report, April 1997.

Department of Environmental Health University of Cincinnati, Leadville/Lake County Environmental Health Lead Study Final Report, April 1997.

Robert Bornschein, Ph.D., Clark, S., Pan W., Succop, P., Midvale Community Lead Study Final Report, Department of Environmental Health University of Cincinnati Medical Center, July 1990.

U.S. Department of Health and Human Services Public Health Service, Agency for Toxic Substances and Disease Registry, Final Report Lead and Cadmium Exposure Study Galena Kansas, January 1996.

U.S. Environmental Protection Agency, Final Evaluation of the Risk from Lead and Arsenic Sandy Smelter Site, Sandy, Utah, December 1995.

Department of Environmental Health University of Cincinnati and Butte-Silver Bow Department of Health, The Butte-Silver Bow County Environmental Health Lead Study Final Report, February 1992.

Amy Rock Wohl, Ph.D., Toxics Epidemiology Program Los Angeles Department of Health Services, The Impact of a Los Angeles County Stationary Lead Source on the Blood Lead Levels of Children Living Nearby Final Report, February 1994.

U.S. Department of Health and Human Services Public Health Service, Agency for Toxic Substances and Disease Registry, Final Report Technical Assistance to the Missouri Department of Health Jefferson City, Missouri Missouri Respiratory Study: Forest City and Glover, Missouri, May 1995.

U.S. Department of Health and Human Services Public Health Service, Agency for Toxic Substances and Disease Registry, Cherokee County Kansas Lead Surveillance Program, April 1998.

U.S. Department of Health and Human Services Public Health Service, Agency for Toxic Substances and Disease Registry, Final Report Technical Assistance to the Idaho State Health Department and the Indian Health Service The Relation of Human Levels of Lead and Cadmium to the Consumption of Fish Caught in and Around Lake Coeur D'Alene, Idaho, September 1989.

U.S. Department of Health and Human Services Public Health Service, Agency for Toxic Substances and Disease Registry, A Cohort Study of Current and Previous Residents of the Silver Valley: Assessment of Lead Exposure and Health Outcomes, August 1997.

U.S. Department of Health and Human Services Public Health Service, Agency for Toxic Substances and Disease Registry, Final Report McClellan Air Force Base Cross-Sectional Health Study Sacramento, Sacramento County, California, January 1996.

U.S. Department of Health and Human Services Public Health Service, Agency for Toxic Substances and Disease Registry, Ottawa County Blood Lead Testing Project, July 1997.

U.S. Department of Health and Human Services Public Health Service, Agency for Toxic Substances and Disease Registry, Final Report Health Study of Communities Surrounding Otis Air National Guard Base/Camp Edwards Falmouth, Massachusetts, March 1998.

U.S. Department of Health and Human Services Public Health Service, Agency for Toxic Substances and Disease Registry, Final Report Technical Assistance to the Pennsylvania Department of Health Study of Disease and Symptom Prevalence in Residents of Yukon and Cokesburg, Pennsylvania, May 1990.

U.S. Department of Health and Human Services Public Health Service, Agency for Toxic Substances and Disease Registry Lead and Mercury Exposure Screening of Children in Pompton Lakes, March 1998.

Appendix D

Models to Predict Blood Lead Levels

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Models to Predict Blood Lead Levels

Models to Predict Blood Lead Levels

Lead in the air contributes to exposure through other pathways because airborne lead can contaminate soil, dust, water, and food. Therefore, characterization of direct inhalation alone is not sufficient.

The following models have been developed specifically to predict blood lead through multimedia pathways. In this Appendix, we discuss the aggregate model, and two disaggregate models, referred to as the Integrated Exposure Uptake Biokinetic (IEUBK) model and the Lead-Spread model. This Appendix describes each model and its applicability.

A. *Aggregate model*

An aggregate model is a reasonably simple way to develop an air lead/blood lead relationship (slope), because it does not require pathway-specific information. It is based on the comparison of two populations exposed to two different air lead concentrations, or the same population at two different air lead concentrations. It accounts for both direct inhalation and secondary routes of exposure. The aggregate approach does not attempt to quantify separately the contribution of airborne lead to soil, water, dust, and food. This model incorporates both the direct and indirect contribution of air concentrations to blood lead levels (BLL) without calculating each component individually. These slopes are used to calculate the increased BLL due to increases in air lead concentration due to emissions from a new or existing source increase, they can not be used to calculate baseline BLLs.

The Office of Environmental Health Hazard Assessment (OEHHA) has used the aggregate model to calculate blood lead/air lead slopes for adults and for children. The OEHHA recommends the use of a slope of 1.8 $\mu\text{g}/\text{dL}$ per $\mu\text{g}/\text{m}^3$ of airborne lead for adults and 4.2 $\mu\text{g}/\text{dL}$ per $\mu\text{g}/\text{m}^3$ for children (ARB, 1997). These blood lead/air lead slopes are used to calculate the change in BLLs due to a change in the airborne lead concentrations. They can be used with the baseline blood lead distributions from this guidance, or site-specific blood lead studies, to predict a change in blood lead and related effects that would result from a change in air lead concentrations. We have also recommended the use of 2.0 $\mu\text{g}/\text{dL}$ per $\mu\text{g}/\text{m}^3$ in limited circumstances to represent inhalation only exposure for children. The number is derived from inhalation studies of adults. It was not recommended in the identification process because the need for this value was not recognized until the identification process was complete.

B. Disaggregate models

A disaggregate model uses a multivariate approach to predict blood lead concentrations. In this approach, the contribution of each variable is estimated separately. This requires separate variables for each component of the non-inhalation exposure. The errors and uncertainties in each component of the disaggregate approach will reduce the precision of an estimate derived from a disaggregate model. This approach is recommended only when there is adequate information on exposure through each pathway (soil, dust, food, and water). This kind of model can be used to calculate a baseline blood lead level. We recommend such an approach as a "Tier II" analysis, to determine neurodevelopmental and/or cardiovascular effects when the facility believes that an analysis based on actual soil and dust lead levels will result in a more accurate estimate of risk. An example of a Tier II disaggregate model is the IEUBK.

1. The IEUBK model

The United States Environmental Protection Agency (U.S. EPA) developed the IEUBK model for lead in children to predict blood lead on the basis of lead concentrations in air, soil, dust, water, and food. We recommend in this guidance that this model be used in the "Tier II" analysis to calculate BLLs of children to age 7.

The inputs for this model can be concentrations in the child's environment, or default values derived from studies deemed applicable by the model's developers. The model allows the user to make rapid calculations of an extremely complex set of equations describing exposure, uptake, and biokinetic functions. It was initially designed to evaluate blood lead distributions in potential soil clean-up actions. It can also be used to predict the impacts on blood lead distributions from various exposure scenarios and assist in evaluating remediation strategies for lead in the human environment. The IEUBK model predicts the likely geometric mean and, assuming an inter-individual geometric standard deviation (GSD) of 1.6, produces a distribution of BLLs that may occur in a child or children given the exposure to lead at 1 residence. The geometric mean of that distribution represents the most likely BLL for the child. The model can also be used to generate a probability of exceeding a BLL of concern. It is applicable only to children up to age 7. Where distinct subgroups have different environmental exposures, the overall risk can be calculated by running the model for each subgroup and using the model to aggregate the results. The aggregate distribution will have a larger GSD because of the range of environmental concentrations.

The ability of these models to predict the blood lead of an individual is limited and will produce a probability distribution rather than a single number. This distribution is described mathematically with a mean and a GSD. The GSD defines the spread of the probabilities which represents the variability. For an individual, this variability reflects individual differences in absorption, excretion, behavioral traits affecting ingestion and inhalation, and measurement error. For a population, the GSD characterizes both the individual variability and the variability in the

concentrations to which the members are exposed. The blood lead distributions generated by the IEUBK model using an inter-individual GSD of 1.6 are based on empirical data on the variability of blood lead levels in children exposed to similar concentrations of lead. In exceptional cases, the GSD can be altered in the model to fit assumptions about the underlying variability. However, the guidance manual for the IEUBK model cautions against changing the default GSD. The manual states that, “The GSD value reflects child behavior and biokinetic variability. Unless there are great differences in child behavior and lead biokinetics among different sites, the GSD values should be similar for all sites, and site-specific GSD values should not be needed.”

Appendix E

Calculations for Changes in the Geometric Mean

Appendix E

Calculations for Changes in the Geometric Mean

Calculations of the change in the geometric mean blood lead levels (BLLs) and the probability of BLLs ≥ 10 $\mu\text{g/dL}$, and the effect of a given level of lead in the air and are illustrated in this Appendix. These calculations were used to create Tables 1 and 2 in Chapter II and Table F-1 in Appendix F. They are used to estimate neurodevelopmental risk. In this Appendix, we provide an example of how to calculate changes in geometric mean (GM). The example calculations start with the baseline for the high exposure scenario, a GM of 3.69 $\mu\text{g/dL}$, and a geometric standard deviation (GSD) of 1.84. The baseline incorporates the background air lead so the air lead concentrations to be used to calculate the increased BLLs are the air lead concentrations attributable to the emissions from the facility being evaluated. To estimate the increased risk from an increase in the air lead concentrations, the GM is converted to an arithmetic mean to reflect the increase in BLL. The GSD is assumed to remain constant.

1. The geometric mean of 3.69 $\mu\text{g/dL}$ and GSD of 1.84 are to an arithmetic mean. The following equation (equation 1) is used:

$$\mu_C = \exp [\ln(\mu_G) + \frac{1}{2} * ((\ln(\sigma_G))^2)] \quad [\text{Equation 1}]$$

where: $\ln(\mu_G) = \ln(3.69) = 1.306$, and $\ln(\sigma_G) = \ln(1.84) = 0.610$
then: $\mu_C = \exp [1.306 + \frac{1}{2} * (0.610)^2] = 4.45$

2. To calculate the arithmetic mean at an increased concentration, add the expected increase in air lead concentration (eg. 0.12 $\mu\text{g/m}^3$) is multiplied by the blood lead/air lead slope of 4.2. This value is added to the calculated arithmetic mean then converted back to the GM.

$$\begin{aligned} &= 4.45 + (0.12 * 4.2) \\ &= 4.95 \end{aligned}$$

3. To get the GM at an air lead concentration of 0.12 $\mu\text{g/m}^3$, put calculated new arithmetic mean into equation 1 and solve for μ_G .

$$\begin{aligned} \mu_C &= \exp [\ln(\mu_G) + \frac{1}{2} * ((\ln(\sigma_G))^2)] \\ 4.95 &= \exp [\ln(\mu_G) + \frac{1}{2} * (0.610^2)] \\ 4.95 &= \exp [\ln(\mu_G) + 0.186] \\ \ln(4.95) &= \ln(\mu_G) + 0.186 \\ 1.60 &= \ln(\mu_G) + 0.186 \\ \ln(\mu_G) &= 1.414 \\ \mu_G &= 4.11 \end{aligned}$$

4. Next, we can calculate a standardized normal deviate or Z-score, which will determine the percent of the distribution above a given level.

$$\begin{aligned} Z &= (\ln(10) - \ln(\mu_G)) / \ln(\sigma_G) \\ Z &= (\ln(10) - \ln(4.11)) / \ln(1.84) \\ Z &= 1.46 \end{aligned} \quad \text{[Equation 2]}$$

Using a normal table, a Z-score of 1.46 is associated with 7.21 percent. That is, based on the normal distribution, we standardize, and estimate that 7.21 percent of the population will be above 10 given a GM of 4.11 µg/dL and a GSD of 1.84.

5. Calculate arithmetic means for increases in air lead concentrations of 0.05, 0.10, 0.15, 0.20, 0.25, 0.5, and 1.0 µg/m³ respectively, starting at a baseline BLL. The associated arithmetic means, for example, for an air lead of 0.15 µg/m³ is:

$$4.45 + (0.15) * (4.2) = 5.08$$

6. Calculate geometric means by substituting arithmetic means into equation 1 and solving for μ_G .
7. Calculate percent above 10 µg/dL using equation 2 to calculate a Z-score and looking up the result in a table of normal distribution values which can be found in most statistics textbooks.

Summary of Calculations

The arithmetic mean associated with a GM of 3.69 µg/dL and a GSD of 1.84 is 4.45 µg/dL. Assuming a blood lead to air lead slope of 4.2 µg/dL per µg/m³, the current contribution of the mean ambient air lead concentration is incorporated in the baseline BLL. A new GM was calculated to incorporate the air concentrations due to the emissions of a facility. A z-score was calculated to determine that emissions from a facility that caused an increase in the air lead of 0.12 µg/m³ would result in 7.21 percent of the population being above 10 µg/dL. Geometric means and risk values for Tables 1 and 2 in Chapter II were calculated using this procedure.

Appendix F

Instructions for Estimating Neurodevelopmental Risk from Short Term Operations

Appendix F

Instructions for Estimating Neurodevelopmental Risk from Short Term Operations

In this Appendix, we describe a process for evaluating neurodevelopmental risk for a source planning to operate less than 30 days. An example of a source operating less than 30 days is a fire department training burn on a building with lead paint. The process is similar to a Tier I neurodevelopmental assessment but uses a blood lead/air lead slope of 2.0¹ to represent only the inhalation risk and not the additional risk from long-term accumulation in dust and soil due to deposition from the air.

Using an appropriate air dispersion model, estimate the 30-day average air concentration that the most highly exposed neighborhood would be expected to experience as a result of the emissions. Use Table F-1 to find percent risk of having blood lead levels at or over 10 µg/dL for the exposed population.

¹ This value was recommended by OEHHA for this purpose subsequent to the identification of lead as a Toxic Air Contaminant. It is based on direct inhalation studies of lead exposure in adults.

Table F-1 Percentage and Geometric Mean of Children with Blood Lead Levels $\geq 10 \mu\text{g}/\text{m}^3$ due to Inhalation Only¹ for Various Air Lead Concentrations at Two Exposure Scenarios

Air Lead Concentration ($\mu\text{g}/\text{m}^3$)	High Exposure Scenario ²		Average Exposure Scenario ³	
	Percent $\geq 10 \mu\text{g}/\text{dL}$	Geometric Mean BLL ($\mu\text{g}/\text{dL}$)	Percent $\geq 10 \mu\text{g}/\text{dL}$	Geometric Mean BLL ($\mu\text{g}/\text{dL}$)
<i>baseline</i> ⁴	5.1	3.69	1.2	3.13
0.02	5.3	3.72	1.3	3.16
0.06	5.6	3.79	1.5	3.23
0.10	5.9	3.85	1.7	3.30
0.20	6.8	4.02	2.1	3.48
0.25	7.1	4.07	2.3	3.57
0.50	9.7	4.52	3.9	4.00
0.75	12.3	4.93	5.9	4.44
1.0	15.2	5.35	8.4	4.88
1.5	21.5	6.18	14.2	5.75

1. Assumes slope of 2.0 (direct inhalation only).
2. High exposure baseline (GM = $3.69 \mu\text{g}/\text{dL}$, GSD = 1.84) is from the blood lead study for Butte Montana, Area A.
3. Average exposure baseline (GM = $3.13 \mu\text{g}/\text{dL}$, GSD = 1.68) is from the unexposed comparison area for the Galena, Kansas Lead Exposure Study.
4. The baseline represents BLLs due to lead in soil, dust, water, food, and background air lead levels.

Appendix G

Statistical Tables for Selecting Sample Size

Appendix G

Statistical Tables for Selecting Sample Size

Table G-1 presents a matrix that can be used to estimate the number of blood lead samples needed to characterize the geometric mean of a log-normal distribution. The sample size is based on a specified level of confidence, a geometric standard deviation you believe the data will have, and the acceptable deviation from the true mean. The table contains matrices for four levels of confidence: 80 percent, 90 percent, 95 percent, and 99 percent. The number to be sampled is found at the intercept of the expected geometric standard deviation and the acceptable multiple of the geometric mean. The acceptable multiple of the geometric mean relates to the desired accuracy. You would use the column for a multiple of 2.0 if it was acceptable for the measured value to be off by as much as 100 percent i.e., if the true value was 5 the measured value could be as much as 10 or as little as 0.

Table G-2 can be used to determine the minimum sample size needed to characterize the number of children with blood lead levels (BLLs) over 10 µg/dL. Table G-2 presents matrices for the same four confidence levels. In the matrix corresponding to the desired level of confidence you would find the intersection between a proportion (p) above 10 µg/dL you believe the data will have, and an acceptable margin of error delta (the deviation from the true value). For example, for a confidence level of 90 percent, believing the fraction of the population with blood lead levels ≥ 10 µg/dL is 3 percent (0.03), you would need a sample size of 787 to achieve an accuracy of + or - 0.01 of the true value.

Adjustment for Small Populations

Tables G-1 and G-2 serve to determine the initial uncorrected sample size for studying the geometric mean and the proportion of the population above 10 µg/dL. However, when the population being studied is smaller than the statistically valid sample size, an adjustment is made for a finite population¹.

For Table G-1 use the following:

$n = n_0 (N / (N + n_0))$ where:

n = the adjusted sample size

n_0 = the statistically valid sample size from Table G-1

N = the population size.

¹ Sampling Techniques, third edition Wiley Series in Probability and Mathematical Statistics - Applied, John Wiley & Sons, 1977

For Table G-2 use the following:

$n = n_0 / (1 + (n_0 / N))$, where:

n = the adjusted sample size

n_0 = the statistically valid sample size from Table G-2

N = the population size.

This information is provided to assist districts in the evaluation proposed study plans for blood lead sampling to establish site-specific blood lead distributions.

Table G-1

Confidence Level = 80% 1.2815516

Acceptable multiple (≥ 1) of geometric mean								
Geometric Standard Deviation	1.050	1.100	1.200	1.300	1.400	1.500	1.600	2.000
1.050	2	0	0	0	0	0	0	0
1.250	34	9	2	1	1	0	0	0
1.500	113	30	8	4	2	2	1	1
1.750	216	57	15	7	5	3	2	1
2.000	331	87	24	11	7	5	4	2
2.250	454	119	32	16	10	7	5	2
2.500	579	152	41	20	12	8	6	3
3.000	833	218	60	29	18	12	9	4
3.250	958	251	69	33	20	14	10	5

Confidence Level = 90% 1.6448536

Acceptable multiple (≥ 1) of geometric mean								
Geometric Standard Deviation	1.050	1.100	1.200	1.300	1.400	1.500	1.600	2.000
1.050	3	1	0	0	0	0	0	0
1.250	57	15	4	2	1	1	1	0
1.500	187	49	13	6	4	3	2	1
1.750	356	93	25	12	7	5	4	2
2.000	546	143	39	19	11	8	6	3
2.250	747	196	54	26	16	11	8	4
2.500	954	250	68	33	20	14	10	5
3.000	1372	359	98	47	29	20	15	7
3.250	1579	414	113	55	33	23	17	8

Table G-1 (Cont.)

Confidence Level = 95% 1.959964

Geometric Standard Deviation	Acceptable multiple (≥ 1) of geometric mean							
	1.050	1.100	1.200	1.300	1.400	1.500	1.600	2.000
1.050	4	1	0	0	0	0	0	0
1.250	80	21	6	3	2	1	1	0
1.500	265	70	19	9	6	4	3	1
1.750	505	132	36	17	11	7	5	3
2.000	775	203	56	27	16	11	8	4
2.250	1061	278	76	37	22	15	11	5
2.500	1355	355	97	47	28	20	15	7
3.000	1948	510	139	67	41	28	21	10
3.250	2242	587	161	78	47	32	24	11

Confidence Level = 99% 2.5758293

Geometric Standard Deviation	Acceptable multiple (≥ 1) of geometric mean							
	1.050	1.100	1.200	1.300	1.400	1.500	1.600	2.000
1.050	7	2	0	0	0	0	0	0
1.250	139	36	10	5	3	2	1	1
1.500	458	120	33	16	10	7	5	2
1.750	873	229	63	30	18	13	9	4
2.000	1339	351	96	46	28	19	14	7
2.250	1833	480	131	63	39	27	20	9
2.500	2340	613	168	81	49	34	25	12
3.000	3364	882	241	116	71	49	36	17
3.250	3872	1015	277	134	81	56	42	19

Table G-2

Confidence Level = 80%

delta==>	0.005	0.010	0.020	0.030	0.040	0.050	0.100	0.150	0.200
p									
0.01	650	163	41	18	10	7	2	1	1
0.02	1288	322	80	36	20	13	3	1	1
0.03	1912	478	119	53	30	19	5	2	1
0.04	2523	631	158	70	39	25	6	3	2
0.05	3121	780	195	87	49	31	8	3	2
0.06	3705	926	232	103	58	37	9	4	2
0.07	4277	1069	267	119	67	43	11	5	3
0.08	4835	1209	302	134	76	48	12	5	3
0.09	5380	1345	336	149	84	54	13	6	3
0.10	5913	1478	370	164	92	59	15	7	4
0.11	6432	1608	402	179	100	64	16	7	4
0.12	6937	1734	434	193	108	69	17	8	4
0.13	7430	1858	464	206	116	74	19	8	5
0.14	7910	1977	494	220	124	79	20	9	5
0.15	8376	2094	524	233	131	84	21	9	5
0.16	8829	2207	552	245	138	88	22	10	6
0.17	9270	2317	579	257	145	93	23	10	6
0.18	9697	2424	606	269	152	97	24	11	6
0.19	10110	2528	632	281	158	101	25	11	6
0.20	10511	2628	657	292	164	105	26	12	7
0.25	12318	3079	770	342	192	123	31	14	8
0.30	13796	3449	862	383	216	138	34	15	9
0.35	14946	3736	934	415	234	149	37	17	9
0.40	15767	3942	985	438	246	158	39	18	10
0.45	16260	4065	1016	452	254	163	41	18	10
0.50	16424	4106	1026	456	257	164	41	18	10

Table G-2 (Cont.)

Confidence Level = 90%

delta==>	0.005	0.010	0.020	0.030	0.040	0.050	0.100	0.150	0.200
p									
0.01	1071	268	67	30	17	11	3	1	1
0.02	2121	530	133	59	33	21	5	2	1
0.03	3149	787	197	87	49	31	8	3	2
0.04	4156	1039	260	115	65	42	10	5	3
0.05	5141	1285	321	143	80	51	13	6	3
0.06	6104	1526	381	170	95	61	15	7	4
0.07	7045	1761	440	196	110	70	18	8	4
0.08	7965	1991	498	221	124	80	20	9	5
0.09	8863	2216	554	246	138	89	22	10	6
0.10	9740	2435	609	271	152	97	24	11	6
0.11	10595	2649	662	294	166	106	26	12	7
0.12	11428	2857	714	317	179	114	29	13	7
0.13	12240	3060	765	340	191	122	31	14	8
0.14	13030	3257	814	362	204	130	33	14	8
0.15	13798	3450	862	383	216	138	34	15	9
0.16	14545	3636	909	404	227	145	36	16	9
0.17	15270	3818	954	424	239	153	38	17	10
0.18	15974	3993	998	444	250	160	40	18	10
0.19	16655	4164	1041	463	260	167	42	19	10
0.20	17315	4329	1082	481	271	173	43	19	11
0.25	20292	5073	1268	564	317	203	51	23	13
0.30	22727	5682	1420	631	355	227	57	25	14
0.35	24620	6155	1539	684	385	246	62	27	15
0.40	25973	6493	1623	721	406	260	65	29	16
0.45	26785	6696	1674	744	419	268	67	30	17
0.50	27055	6764	1691	752	423	271	68	30	17

Table G-2 (Cont.)

Confidence Level = 95%

delta==>	0.005	0.010	0.020	0.030	0.040	0.050	0.100	0.150	0.200
p									
0.01	1521	380	95	42	24	15	4	2	1
0.02	3012	753	188	84	47	30	8	3	2
0.03	4471	1118	279	124	70	45	11	5	3
0.04	5900	1475	369	164	92	59	15	7	4
0.05	7299	1825	456	203	114	73	18	8	5
0.06	8666	2167	542	241	135	87	22	10	5
0.07	10003	2501	625	278	156	100	25	11	6
0.08	11309	2827	707	314	177	113	28	13	7
0.09	12585	3146	787	350	197	126	31	14	8
0.10	13829	3457	864	384	216	138	35	15	9
0.11	15043	3761	940	418	235	150	38	17	9
0.12	16226	4057	1014	451	254	162	41	18	10
0.13	17379	4345	1086	483	272	174	43	19	11
0.14	18500	4625	1156	514	289	185	46	21	12
0.15	19591	4898	1224	544	306	196	49	22	12
0.16	20652	5163	1291	574	323	207	52	23	13
0.17	21681	5420	1355	602	339	217	54	24	14
0.18	22680	5670	1417	630	354	227	57	25	14
0.19	23648	5912	1478	657	370	236	59	26	15
0.20	24585	6146	1537	683	384	246	61	27	15
0.25	28811	7203	1801	800	450	288	72	32	18
0.30	32268	8067	2017	896	504	323	81	36	20
0.35	34957	8739	2185	971	546	350	87	39	22
0.40	36878	9220	2305	1024	576	369	92	41	23
0.45	38030	9508	2377	1056	594	380	95	42	24
0.50	38415	9604	2401	1067	600	384	96	43	24

Table G-2 (Cont.)

Confidence Level = 99%

delta==>	0.005	0.010	0.020	0.030	0.040	0.050	0.100	0.150	0.200
p									
0.01	2627	657	164	73	41	26	7	3	2
0.02	5202	1300	325	144	81	52	13	6	3
0.03	7723	1931	483	215	121	77	19	9	5
0.04	10191	2548	637	283	159	102	25	11	6
0.05	12606	3152	788	350	197	126	32	14	8
0.06	14968	3742	936	416	234	150	37	17	9
0.07	17277	4319	1080	480	270	173	43	19	11
0.08	19533	4883	1221	543	305	195	49	22	12
0.09	21736	5434	1358	604	340	217	54	24	14
0.10	23886	5971	1493	663	373	239	60	27	15
0.11	25982	6496	1624	722	406	260	65	29	16
0.12	28026	7006	1752	778	438	280	70	31	18
0.13	30016	7504	1876	834	469	300	75	33	19
0.14	31954	7988	1997	888	499	320	80	36	20
0.15	33838	8459	2115	940	529	338	85	38	21
0.16	35669	8917	2229	991	557	357	89	40	22
0.17	37447	9362	2340	1040	585	374	94	42	23
0.18	39172	9793	2448	1088	612	392	98	44	24
0.19	40844	10211	2553	1135	638	408	102	45	26
0.20	42463	10616	2654	1180	663	425	106	47	27
0.25	49762	12440	3110	1382	778	498	124	55	31
0.30	55733	13933	3483	1548	871	557	139	62	35
0.35	60378	15094	3774	1677	943	604	151	67	38
0.40	63695	15924	3981	1769	995	637	159	71	40
0.45	65685	16421	4105	1825	1026	657	164	73	41
0.50	66349	16587	4147	1843	1037	663	166	74	41

Appendix H

Basis and Rationale for Risk Management Levels

Appendix H

Basis and Rationale for Risk Management Levels

1. Risk Management Levels

In the permitting process, the districts make decisions about the need for control technology and whether new sources or modifications to existing sources can be permitted. For this purpose, the district identifies the following risk levels:

- 1) Toxic Best Available Control Technology (T-BACT) trigger level. This is the risk level at which the district would require a source to install T-BACT on the new source or the new equipment at an existing source.
- 2) Approvable level. Below this level, the district could approve a new source or modification to an existing source without a Specific Findings Report.
- 3) Permit denial level. At a risk equal to or above this level, the district would not issue a permit.

For the Hot Spots Program, recommendations are needed for the following risk management levels:

- 1) Notification level. This is the risk level at which facilities need to notify the exposed population (this could be the same as the significant risk level).
- 2) Significant risk level. At this level, facilities would be required to implement a risk reduction audit and plan. The risk reduction audit and plan must show how the facility will reduce the risks to below this level within 5 years. The district may lengthen the implementation period up to an additional five years if that additional time will not result in an unreasonable risk and compliance within 5 years is not technically feasible and economically practicable .
- 3) Unreasonable risk level. Facilities with risks at or above this level must reduce their risks within five years or less. The district may shorten the implementation period if it is technically feasible and economically practicable or if the emissions from the facility pose an unreasonable risk.

2. Basis for Consideration of Risk Management Recommendations

The U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (CDC) has declared that the goal of all lead poisoning prevention activities should be to reduce children's blood lead levels (BLLs) below 10 µg/dL (CDC, 1991). If many children in

the community have BLLs ≥ 10 $\mu\text{g/dL}$, communitywide interventions (primary prevention activities) should be considered by appropriate agencies. Interventions for individual children should begin at BLLs of 15 $\mu\text{g/dL}$. There are a range of recommended actions based on the BLLs. Within the 15-19 $\mu\text{g/dL}$ range of BLLs, a child should be given nutritional and educational intervention and more frequent screening. If BLLs in this range persist, environmental investigation and intervention are recommended. BLLs within the 20-44 $\mu\text{g/dL}$ range trigger a recommendation for environmental investigation and intervention, and a medical evaluation. At BLLs within the 45-69 $\mu\text{g/dL}$ range, the recommendation is for both environmental and medical intervention, including chelation therapy. BLLs over 70 $\mu\text{g/dL}$ constitute a medical emergency and require immediate environmental and medical intervention.

The Department of Toxic Substances Control (DTSC) in the California Environmental Protection Agency has identified a one percent risk of exceeding 10 $\mu\text{g/dL}$ as the “point of departure”, i.e., starting point, for decisions about soil clean-up (DTSC, 1996). This might be considered to be analogous to a 1 in a million cancer risk, generally regarded as a level below which no action need be taken. At levels above this, other factors such as land use, technical feasibility, or cost might be considered by DTSC in determining appropriate risk management actions.

The United States Environmental Protection Agency (U.S. EPA) has been directed to establish “screening levels” for lead in soil. The screening level is a level above which site-specific analysis is recommended to establish clean-up goals. In considering what to set as screening levels, the U.S. EPA evaluated soil concentrations which would “pose a risk” to a typical (or hypothetical) child or group of similarly exposed children. The level U.S. EPA considered to “pose a risk” was defined as the concentration at which children had no more than a 5 percent chance of BLLs ≥ 10 $\mu\text{g/dL}$ (U.S. EPA, 1998). In developing the residential screening level, the Office of Solid Waste and Emergency Response (OSWER) applied the U.S. EPA’s IEUBK model on a site-specific basis. The model generates a probability distribution of BLLs for a typical child, or group of children, exposed to a particular soil lead level and concurrent lead exposure from other sources. This would be an individual risk for the child in a specific residence. This is an approach that fits well with the purpose of determining whether the soil at a particular location needs to be removed or covered.

The federal Ambient Air Quality Standard (AAQS) for lead was originally set at a level that was designed to prevent 99.95 percent of children from exceeding a BLL of 25 $\mu\text{g/dL}$, which was at that time the level of concern. Using protection of 99.95 percent of children as a precedent, it might be reasonable to base an assessment of significance on the percentage increase in the number of children expected to have BLLs ≥ 10 $\mu\text{g/dL}$. However, the data on current blood lead levels in children indicate that this level of protection could not be achieved even if there were no exposure to lead in air because of the other sources of exposure which contribute to children’s BLLs.

3. Rationale for the Risk Management Levels for the Simplified Approach

In consideration of the complexity of estimating risk for two different types of health effects using two different averaging times for the dispersion modeling, we are proposing an alternative procedure. In this procedure, the 30-day average air concentration at the point of maximum impact would be compared to air concentrations representing risk management levels. We chose to use the 30-day average at the point of maximum impact because that makes this approach a little more conservative than the detailed approach for most facilities. For the Hot Spots Program, $0.30 \mu\text{g}/\text{m}^3$ is recommended as the notification and significant risk level and $0.55 \mu\text{g}/\text{m}^3$ as the unreasonable risk level. For permitting, $0.30 \mu\text{g}/\text{m}^3$ is recommended as the approvable level and $0.55 \mu\text{g}/\text{m}^3$ as the permit denial level. We chose these air concentrations in consideration of the recommended neurodevelopmental risk management levels and the associated cardiovascular risk. They are moderately conservative for all sources except those impacting neighborhoods with a high potential for exposure from other sources. Therefore, we do not recommend their use in areas that would fit the high exposure scenario for neurodevelopmental effects.

4. Rationale for the Risk Management Levels for Neurodevelopmental Effects

The precedents cited, thus far, are based on a calculation of individual risk. This is an appropriate approach for making decisions about whether to clean up the lead at an individual residence or specific location. Risk management for lead emitted to the air from stationary sources differs from risk management for lead in soil. Soil lead is relatively stationary, while lead emitted to the air from a stationary source can increase the exposure of a whole community. Air quality models are used to predict the location and concentration of the resulting lead in the air and are used to predict the point of maximum impact. However, the actual impact of air emissions on exposure cannot be predicted so precisely. In the case of lead, where the contribution from the air lead may be small in comparison to the exposures from other sources, it may be more realistic to evaluate the neurodevelopmental effects for an area rather than for the “maximally exposed individual”.

It is possible to calculate the change in the mean BLL for an exposed neighborhood or community but there is little agreement about the significance of “averaged” increases in BLLs. Therefore, we are recommending that the risk (probability) of $\text{BLLs} \geq 10 \mu\text{g}/\text{dL}$ for the maximum exposure area be evaluated.

Hot Spots Program

The notification level for the Hot Spots Program is recommended at a 5 percent risk of $\text{BLLs} \geq 10 \mu\text{g}/\text{dL}$. This is consistent with U. S. EPA’s statement that a risk between 1 and 5 percent probability “poses a threat” to children living in a lead contaminated home. The U.S. EPA also concluded that in the context of determining hazardous levels of lead in soil and dust, it was not possible to distinguish between 1 and 5 percent risk due to the uncertainty and variability

associated with relating lead in the environment to blood lead concentrations. To avoid a situation where all sources of lead located in or near a high exposure area would have to make notification, we are recommending an alternative level that allows the consideration of the fraction of the mean BLL the facility contributes. In proposing the level for the facility contribution, we considered the other routes of exposure through water, soil, dust, and food. We believe the air lead should not contribute a disproportionate fraction of the risk. We also must consider that the source doing a risk assessment for the Hot Spots Program will not be the only source of air lead. Notification is recommended to be required only for those with a facility contribution ≥ 10 percent.

The significant risk level for an existing source in the Hot Spots Program is recommended to be set at the 5 percent risk of BLLs $\geq 10 \mu\text{g/dL}$. This could present a problem for sources in an area with a high potential for exposure due to other sources. In a high exposure scenario for neurodevelopmental effects, the background risk could be over the 5 percent risk of BLLs $\geq 10 \mu\text{g/dL}$. To avoid a situation in which a source would be required to reduce risks due to other sources, it is recommended the facility contribution is not allowed to exceed 10 percent of the mean BLL in the neighborhood.

In considering what might constitute an unreasonable risk for the Hot Spots Program, we found little regulatory precedent. In 1975, U.S. EPA set a maximum contaminant level for lead in water of 0.05 milligrams per liter. This would result in a 20 percent risk of BLLs $\geq 10 \mu\text{g/dL}$. This was re-evaluated in 1991 and the U.S. EPA declined to set a maximum contaminant level because there is no known threshold below which lead health effects would not be expected. In consideration of risk levels associated with dangerous levels of lead, the highest probability considered by U.S. EPA was 10 percent. This level would be associated with a probability of 1.6 percent that children would have a blood lead level $\geq 15 \mu\text{g/dL}$. The U.S. EPA found this unacceptable and we concur and are proposing a 10 percent risk of BLLs $\geq 10 \mu\text{g/dL}$ as the unreasonable risk level.

Permit Decisions

Several approaches were considered for setting a T-BACT trigger level. Because there is no safe threshold for neurodevelopmental effects of lead, we considered a zero T-BACT trigger. This approach would require any source seeking a permit for a new source or a modification that would emit lead to install T-BACT. Theoretically, this would require T-BACT for any manufacturer that did small amounts of soldering or casting, for small combustion sources, or for any new firing range. We also considered setting a risk based T-BACT trigger level. For instance, a 1 percent individual risk of having a BLL $\geq 10 \mu\text{g/dL}$ similar to the DTSC's "point of departure" as discussed earlier. However, we believe a T-BACT trigger should apply to all facilities equally, not depend on whether a new source was proposed for an area with a high potential for exposure due to other sources.

Another approach we considered was a T-BACT trigger level based on an air concentration. An increase of $0.02 \mu\text{g}/\text{m}^3$ would double the average exposure based on the population-weighted statewide ambient average concentrations. However, that approach would require a new source that emitted even very small quantities of lead to do air dispersion modeling. A simpler approach for both the sources and the districts would be a T-BACT trigger based on an emission rate. For sources with no stack, an emission rate of 1 pound per month could result in an air concentration of $0.02 \mu\text{g}/\text{m}^3$. Using this emission rate as the T-BACT trigger would ensure a consistent level of protection and protection for children in neighborhoods with a high potential for exposure.

In terms of permitting, we believe that if a permit is issued for a source with risks above the significant level, the reasons for issuing the permit should be documented and made public. We further believe there should be a level above which a source should not be issued a permit. The U.S. EPA finds that a probability of BLLs $\geq 10 \mu\text{g}/\text{dl}$ between 1 and 5 percent poses a risk. However, they also found that it was not possible to reliably distinguish between a 1 percent and a 5 percent probability. This was due to measurement variability, individual variability and the uncertainties in the modelling process. We considered these factors and the findings of the NHANES study (see Appendix A) that two percent of the children in the western region have BLLs $\geq 10 \mu\text{g}/\text{dl}$. These considerations lead us to recommend a probability of 5 percent as the approvable level. Therefore, if the risk equals or exceeds 5 percent, a decision to permit the source should be accompanied by a justification in a Special Findings Report issued by the district.

We are recommending the permit denial level be a 10 percent probability of BLLs $\geq 10 \mu\text{g}/\text{dl}$. This is consistent with our recommended unacceptable level and was recommended on the basis of similar considerations.

6. Rationale for the Risk Management Recommendations for Cancer

For cancer risk, we are proposing the same risk management levels as in the Risk Management Guidance; a T-BACT trigger of 1 in a million, an approvable level of 10 in a million and a permit denial level of 100 in a million. For the Hot Spots Program, we are proposing a public notification level and significant risk level of 10 in a million and an unreasonable risk level of 100 in a million.

Significance levels for cancer effects have evolved over the past several years. For many districts, less than 1 in a million cancer risk would not trigger use of toxics best available control technology (T-BACT). One hundred in a million, however, is generally considered unacceptable for permitting purposes. Above the 1 in a million level, district new source toxic regulations often require installation of T-BACT. Districts generally require public notification in the Hot Spots Program at a cancer risk of 10 in a million. Individual districts have adopted significant risk levels ranging from 10 to 100 in a million but there is general agreement on an unreasonable risk level of 100 in a million.

Appendix I

Specific Findings and a Specific Findings Report

Appendix I

Specific Findings and a Specific Findings Report¹

Specific Findings Report

We suggest submitting a Specific Findings Report to the Air Pollution Control Officer (APCO) if the non-cancer and/or cancer risk for a new or modified source is greater than the approvable level. The Specific Findings Report provides the APCO with information upon which he or she can decide whether the permit should be granted.

We believe it is important for the APCO to identify and make available to the public the written findings which support the decision to permit or not permit a source. The APCO may also wish to conduct a public meeting to receive comment from affected parties. Listed below are definitions of key terms and examples of the type of information that may be included in the report.

1. Key Terms

a. Feasible Reduction Measures

Feasible reduction measures are control measures and techniques that are technologically feasible and economically practicable and include, but are not limited to, changes of basic control equipment, product substitution or modification, process modifications, feedstock modifications, operation and maintenance improvements, and enclosing systems or processes to reduce emissions. Feasible reduction measures are different from T-BACT in that they apply to existing permit units. They are similar to T-BACT in that feasibility is determined on a case-by-case basis.

b. Beyond T-BACT

Beyond T-BACT describes any combination of control measures that are needed to reduce a source's potential risk below an applicable criterion value. Beyond T-BACT may include more effective control measures than the measures listed in the definition of T-BACT as well as enforceable limitations on the potential to emit.

¹ Adapted from the ARB's Risk Management Guidelines for New and Modified Sources of Toxic Air Pollutants, July 1993

2. Content

- a. Identify pollutants that would be emitted.

The report should identify and quantify the toxic air pollutants that would be emitted from the source.

- b. Identify the health impact of the toxic pollutant(s) that would be emitted.

The cancer and non-cancer risk associated with the toxics that would be emitted from the new or modified source should be identified and discussed. The applicant may also wish to discuss potential cancer burden as a measure of communicating the magnitude of the potential cancer risk. As specified in the CAPCOA Air Toxics “Hot Spots” Program Risk Assessment Guidelines, (October, 1993) the permit applicant should also discuss how currently undeveloped areas are “zoned” (i.e. commercial or residential) and use this information to estimate potential health impacts should this area be developed. The applicant may wish to present information on the likelihood that an individual could reside at the point of maximum off-site cancer risk.

- c. Discuss the uncertainty in the risk assessment process.

The permit applicant may wish to include information regarding uncertainty in the risk assessment process as described in the chemical health effects documents.

- d. Discuss the benefits associated with the new or modified source.

The permit applicant may wish to include information regarding the benefit the new or modified source would provide the local community. Benefits of the source may include the service provided to the community or a decrease in risk compared to risk estimates without the source.

- e. Identify federal, state, or local mandates.

The permit applicant may indicate whether there are any existing federal, state, or local mandates that requires modification of an existing source or establishment of a new source. For example, the state’s clean fuel regulations may require an existing gasoline station to offer clean fuel for sale. In order to comply, the owner of the gasoline station may have to modify the facility to add a clean fuel pump.

- f. Identify multi-media impacts.

The APCO should require the permit applicant to identify the impact the new or modified source may have on media other than air.

- g. Discuss the findings of the California Environmental Quality Act (CEQA) document if one was required for the project.

Independent of these guidelines, the APCO must review environmental impact reports (EIRs) that are prepared by the Lead Agency pursuant to the requirements of the CEQA. This document should provide information regarding background, cumulative, and ecological risk. Background risk is the risk associated with the ambient toxic air pollutant levels due to local stationary sources and mobile sources. Cumulative risk is the sum of the risk of toxic air pollutant emissions from local stationary sources within a given area. Ecological risk is the risk to flora and fauna resulting from emissions of toxic air pollutants.

- h. Identify sensitive receptors impacted by the new or modified source.

The APCO may require the permit applicant to identify any sensitive receptor locations impacted by the toxic air emissions from the new or modified source. A sensitive receptor location includes, but is not limited to, any hospital, school, or day-care center.

- i. Provide a risk reduction plan.

The APCO may require, or the permit applicant may wish to provide, a risk reduction plan identifying all feasible reduction measures to reduce potential risk from the source.

The risk reduction plan should:

- i. Identify which processes and activities cause toxic emissions and what portion of the total potential source risk is due to each.
- ii. Identify all feasible reduction measures and applicable beyond T-BACT measures for the source type.
- iii. Estimate the risk reduction potential of the feasible reduction measures and beyond T-BACT measures.
- iv. Estimate how long it would take to implement the feasible reduction measures and beyond T-BACT measures.

- v. Determine the technical feasibility and cost-effectiveness of the feasible reduction measures and beyond T-BACT measures for the individual source.
- vi. Identify the feasible reduction measures and beyond T-BACT measures that will be implemented to reduce potential risk and a detailed schedule for implementation. If the plan shows that these measures are insufficient to meet the lower risk level, the plan should identify possible reductions in the future.

Appendix J

Regulatory Programs for Lead

Appendix J

Regulatory Programs for Lead

This Appendix presents a summary of past regulatory approaches and actions on airborne lead. It also discusses regulatory programs established to address toxic air contaminants.

Ambient Air Quality Standards

An ambient air quality standard (AAQS) is a regulation designed to protect public health by establishing an allowable air concentration of a pollutant. There are both State and Federal air quality standards for lead. The State AAQS for lead was established in November 1970 following the recommendations of the State Department of Public Health¹. It was based on health effects data that showed exposure to airborne lead levels above 1.5 micrograms per cubic meter ($\mu\text{g}/\text{m}^3$) averaged over a 30-day period could result in the accumulation of lead in the body in quantities sufficient to cause impairment of the blood forming system.

The federal standard was set at 1.5 micrograms per cubic meter ($\mu\text{g}/\text{m}^3$) averaged over a 90-day period. The federal standard was set at a level that would insure that 99.5 percent of children would have a BLL less than 40 micrograms per deciliter ($\mu\text{g}/\text{dL}$). At that time, 40 $\mu\text{g}/\text{dL}$ was considered to be an elevated BLL.

As better data on health effects were developed, public health agencies revised downward the BLL of concern. By 1991, the Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health & Human Services, Public Health Service considered 10 $\mu\text{g}/\text{dL}$ to be an elevated BLL in children. The CDC recommends community intervention (primary prevention activities by the appropriate agencies) if many children in the community have BLLs at or over this level. An example of a primary prevention activity is clean-up of a site with soil contamination even if it has not been established that the site has contributed to the high BLLs detected. The Office of Environmental Health Hazard Assessment (OEHHA) has identified 10 $\mu\text{g}/\text{dL}$ as a level of concern because it is a level at which studies have adequately demonstrated an adverse health effect.

When the Air Resources Board (ARB/Board) reviewed the State AAQS in 1985, changes were made to the measurement methods but the standard was left at 1.5 $\mu\text{g}/\text{m}^3$ over a 30-day averaging time. The United States Environmental Protection Agency (U.S. EPA) reviewed the federal AAQS in 1990 and did not revise it. It remains at 1.5 $\mu\text{g}/\text{m}^3$ over a 90-day averaging time.

¹ The State Department of Public Health is now the Department of Health Services (DHS)

The Toxic Air Contaminant Identification and Control Program

Assembly Bill 1807 (1983) established a program for the identification and control of toxic air contaminants. In this program, risk assessment is separated from risk management. Risk assessment is the process of examining the available evidence on health effects associated with exposure to a substance and relating the probability of adverse health effects to a given exposure level. Risk management is the process of evaluating emission sources to determine the need and appropriate degree of regulation, and if necessary, taking action to reduce emissions.

Under the AB 1807 air toxics identification phase (risk assessment), ARB and OEHHA staffs prepare a report for public review that is the basis for the proposed identification of a substance as a toxic air contaminant (TAC). The identification process involves full public participation including numerous comment periods, workshops, meetings with affected industries, a review by the independent Scientific Review Panel (SRP), and consideration by the Board at a formal public hearing.

Once a substance has been formally identified as a TAC, the risk management phase begins. In the risk management process, ARB staff conduct a regulatory needs assessment. A “needs assessment” is an assessment of the need and appropriate degree of regulation for a substance identified as a TAC. Full public participation is also a feature of the risk management process. ARB staff carries out this evaluation in consultation with the districts, affected sources, and the interested public. Typically, the ARB publishes a report that describes the regulatory needs assessment and summarizes staff recommendations for actions.

The following issues are considered to the extent that data can reasonably be made available:

1. current and future anticipated emission rates, levels of human exposure, and the risk associated with those levels;
2. the stability, persistence, transformation products, dispersion potential, and physical and chemical characteristics of the substance when present in the ambient air;
3. the categories, numbers, and relative contribution of present or anticipated sources of the substance;
4. the availability and technological feasibility of control measures, taking into account the effect of control measures on levels of exposure, and recent technological improvements or other actions which emitting sources have implemented in the recent past to reduce emissions;
5. the cost and cost effectiveness of control measures;
6. the availability, suitability, and efficacy of substitute compounds of a less hazardous nature; and
7. the potential adverse health, safety, or environmental impacts of implementing a control measure.

The Board considers the recommendations made in the regulatory needs assessment. When this analysis indicates a need for additional control, staff--subsequent to Board approval--develop, in cooperation with industry and districts, a proposed control measure for consideration by the Board. In a formal hearing, the Board considers public comments, receives public testimony, and acts on the proposal. Once the statewide control measure is adopted, the districts implement and enforce it, or adopt and enforce one at least as stringent.

The status of lead under AB 1807

ARB and OEHHA evaluated lead for identification as a toxic air contaminant (TAC) under the AB 1807 program. The Board approved the listing of inorganic lead as a TAC at a public hearing April 24, 1997. Lead was listed as a TAC for which a threshold exposure level could not be identified. The threshold exposure level is the level below which adverse health effects are not expected to occur. Lead is the first identified TAC for which non-cancer effects with no threshold have been identified. At that hearing, the Board directed ARB staff to develop risk management guidance to assist districts and industry to evaluate the potential health effects of lead emissions.

The OEHHA's review of available health effects data published in the March 1997 "Technical Support Document, Proposed Identification of Inorganic Lead as a Toxic Air Contaminant, Part B Health Assessment" examined and reported on many studies. The OEHHA noted that a recent study specifically focused on determining a threshold was unable to detect one. The ARB, SRP, and OEHHA concur in the conclusion that a "no observed adverse effect level" (NOAEL) cannot be reliably identified for at least three of the health effects of lead: cancer, cardiovascular effects in adults, and neurological impairment in children. Other reviews of health outcomes associated with lead exposure can be found in the U.S. EPA's "Air Quality Criteria for Lead", published in 1986, and "Air Quality Criteria for Lead: Supplement to the 1986 Addendum", published in 1990; the Agency for Toxic Substances and Disease Registry's "Toxicological Profile for Lead", published in 1990 (currently being revised); and the National Research Council's "Measuring Lead Exposure in Infants, Children, and Other Sensitive Populations", published in 1993.

Regulations affecting lead adopted under AB 1807

Following the identification of cadmium as a toxic air contaminant in January 1987, ARB staff developed an airborne toxic control measure (ATCM) for emissions of toxic metals from non-ferrous metal melting operations. The Board adopted the ATCM in January 1993. It is currently being implemented by affected facilities and by the districts. Because lead is emitted from some of the same facilities that the ATCM affects, lead emissions were also reduced as a result of compliance with that regulation. This is because the ATCM requires reduction in emissions of particulate matter, in which cadmium, lead, and other metals occur.

Need for additional regulations to reduce lead emissions

The ARB staff is currently conducting an evaluation of lead sources, emissions, and risk to determine whether additional control measures are needed for lead. The findings of that assessment will determine staff recommendations as to whether additional actions are necessary.

The Air Toxics “Hot Spots” Program

Assembly Bill (AB) 2588 established the Air Toxics “Hot Spots” Information and Assessment Act (Air Toxics “Hot Spots” Program) in 1987. AB 2588 established requirements for facilities to report their emissions of air toxics including lead. The districts review these reports and then prioritize the facilities based on their potential health risk. Risk assessments are performed for high priority facilities. Facilities with risks that exceed district-specified trigger levels must notify the public. To facilitate risk assessment review and improve statewide consistency, the California Air Pollution Control Officer’s Association (CAPCOA) published risk assessment guidelines.

In 1992, additional requirements were added through adoption of Senate Bill (SB) 1731. The objective of SB 1731 was to require facilities with significant risks to reduce their risks. SB 1731 requires local air districts to designate significant risk levels. Facilities with risks over the significance level are then required to develop a risk reduction audit and plan describing actions they will take to reduce their risks. SB 1731 also directed OEHHA to develop risk assessment guidelines. Finally, SB 1731 directed the ARB to provide assistance to the districts and smaller businesses. To that end, the ARB has produced a general guideline document for all facilities on how to conduct a risk reduction audit and prepare a risk reduction plan, and source-specific guideline documents for chrome plating, aerospace operations, degreasing operations, and autobody shops.

Other Actions to Reduce Lead Exposure

There have been several regulatory actions taken in the last 10 years which have significantly reduced the public’s exposure to lead. Both the ARB and U.S. EPA have acted to reduce lead use in gasoline. The U.S. EPA promulgated a National Emissions Standards for Hazardous Air Pollutants (NESHAP) for Secondary Lead Smelting in 1995 which imposed limits on emissions from stacks and required improved housekeeping and operating procedures to reduce fugitive emissions. The U.S. EPA has promulgated national primary drinking water regulations for controlling lead in drinking water. The U.S. Consumer Products Safety Commission has promulgated limits on lead in consumer products and in paint. These actions have reduced the body burden of lead for U.S. residents. The quantitative effect can be seen in the results of the National Health and Nutritional Examination Surveys (NHANES) which measured blood lead levels at intervals since 1988. See Appendix A for a discussion of the findings of the NHANES studies.

Appendix K

**Form for Reporting a Planned Tier II Study
to the Childhood Lead Poisoning Prevention Branch**

DEPARTMENT OF HEALTH SERVICES
CHILDHOOD LEAD POISONING PREVENTION BRANCH
1515 CLAY STREET, SUITE 1801
OAKLAND, CA 94612
(510) 622-5000



SITE-SPECIFIC ENVIRONMENTAL SAMPLING
AT RESIDENTIAL ADDRESSES NEAR A STATIONARY SOURCE FACILITY
Tier II Data for Permit Application

Please complete this information and fax to Environmental Investigations Unit: (510) 622-5002

1. Complete the following Facility information:

NAME OF FACILITY	
ADDRESS OF FACILITY	
CONTACT NAME/TITLE	
CONTACT PHONE/FAX	
LOCAL APC DISTRICT	
APCD CONTACT NAME/PHONE	
LOCAL HEALTH OFFICER	
DATE HEALTH OFFICER NOTIFIED	

2. Complete the following environmental sampling information:

DATE SAMPLING TO BE CONDUCTED	
TOTAL NUMBER OF ADDRESSES TO BE SAMPLED	
TOTAL NUMBER OF SOIL SAMPLES TO BE COLLECTED	
TOTAL NUMBER OF DUST SAMPLES TO BE COLLECTED	
TOTAL NUMBER OF WATER SAMPLES TO BE COLLECTED	
TOTAL NUMBER OF FOOD SAMPLES TO BE COLLECTED	

3. Attach a table that includes the following information:

EACH ADDRESS TO BE SAMPLED
SOIL SAMPLE LOCATIONS
SOIL SAMPLE RESULTS
DUST SAMPLE LOCATIONS
DUST SAMPLE RESULTS
WATER SAMPLE LOCATIONS
WATER SAMPLE RESULTS
TYPE OF FOOD SAMPLED AND RESULTS

4. Explain what steps the Facility will take for environmental results that exceed regulatory levels

5. Explain how the Property Owner will be notified of lead contaminated soil, dust, and water.